REMARKS/ARGUMENTS

Applicant would like to thank the Examiner for the careful consideration given the present application. Claims 16 and 17 have been amended to more clearly describe the invention. New claims 24-27 have been added to claim additional features supported by the specification. No new matter has been entered. Withdrawn claims 8-10 and 15 have been canceled without prejudice.

1. Election/Restrictions

The Examiner has required Applicant to elect a single invention for prosecution on the merits. In a telephone conference with the Examiner on October 31, 2007 Applicant authorized the provisional election of Invention III, claims 16-23, with traverse. Applicant hereby affirms the election of Inventions III, claim 16-23. New claims 24-27 depend ultimately from claim 16, and hence are also within the scope of Invention III.

2. Claims Rejections

The Examiner has rejected Claims 16-23 under USC 103(a) as being unpatentable over Onuki et al. (U.S. Patent No. 7,063,715) in view of Hirofumi et al. (WO 00/27889, corresponding to U.S. Patent No. 6,806,260) or Sung et al. (U.S. Patent No. 6,624,138). The rejection is traversed for the following reasons.

Onuki discloses two distinct devices. One is a suture apparatus that is the main focus of the Onuki patent, embodiments of which are described throughout the first 12+ columns of the patent and illustrated in the vast majority of the figures (Figs. 1-34). The second device is an injection needle 201, which is described beginning at the middle of column 13. It is important to recognize these are different devices. As explained at col. 13, lines 28-38, *one application* of the suture apparatus in Onuki is to suture mucosal

membranes that were previously subjected to a mucosal resection. Onuki describes an exemplary mucosal-resection technique and the device for performing a mucosal resection. The device for performing a mucosal resection (injection needle 201) is described from column 13, line 39 to column 15, line 35. It is the injection needle 201 that uses saline to provide a bulge in a mucosal membrane. Conversely and separately, the suture device of Onuki uses staples of various forms (based on the different described embodiments) to close (i.e. suture) incised tissue, for example the incision in a mucosal membrane that may be left after a device such as injection needle 201 is used.

Citing the portion of Onuki that describes the injection needle 201, the Examiner has pointed out that Onuki discloses that the injection needle

> is projected from the distal end of the endoscope whereby a physiological saline or other solution is injected under a mucous membrane of an organ by means of the needle. In this paragraph, Onuki et al discloses that the higher the viscosity of the solution, the longer the bulging time of the mucous membrane. Office action, p. 5.

Further recognizing that Onuki does not disclose a solution comprising a chitosan derivative as the bulging agent, the Examiner has relied on Hirofumi to supply this teaching, and to suggest it would have been obvious to substitute the chitosan species from Hirofumi for the saline solution as bulging agent in Onuki. The Examiner's reasoning is as follows:

> Hirofumi et al discloses using the functional chitosan derivative in the medical field as wound dressings, antiadhesive materials, hemostatics, and sealants for body fluids or gases. The description of the use of the functional chitosan derivative as sealants for body fluids or gases falls within the scope of sutures. * * * It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the solution administered by the endoscopic suture apparatus of the Onuki et al patent with a composition comprising a functional chitosan

> derivative in view of the recognition in the art, as evidenced by the Hirofumi et al publication...that chitosan compounds administered via an endoscopic instrument are effective as sealants for body fluids or gases and other medical applications. Office action, pp. 5-6.

Respectfully, the Examiner's reasoning is incorrect. The Examiner has apparently misunderstood the suture apparatus described in the first 12 columns of Onuki to be the same device (i.e. the same endoscope or an embodiment thereof) as the injection needle 201 that is described beginning at column 13. In fact, they are not the same. Moreover, the fact that Hirofumi may disclose chitosan derivatives are functional as wound dressings or sealants is *totally irrelevant* to the function and manner in which the claimed chitosan derivative is used in the present application. In the present claims, the chitosan-derivative solution is used as a bulging agent, wherein it has been discovered that the chitosan-containing materials as-claimed produce an extended bulging time when injected under the mucous membrane. In this application, the chitosan derivative's wound-dressing or sealant properties, even assuming it has them, are totally irrelevant to its effectiveness and use as a bulging agent.

The fact that chitosan compounds as would dressings may or may not be analogous to the staples used in the suture apparatus of Onuki does not provide any reason or suggestion at all to use chitosan derivatives as a bulging agent in the other, different device described in Onuki, the injection needle 201. Those are different devices that perform different functions; one creates an incision (the injection needle 201) while the other closes or sutures the incision (the suturing device, Figs. 1-34).

Once it is recognized that any wound-dressing properties chitosan or its derivatives may have are irrelevant to its use as a bulging agent, it is clear that one of ordinary skill in the art would have had absolutely no reason to consider substituting chitosan derivatives for the saline solution used in Onuki's injection needle 201. The fact that Onuki mentions that a higher-viscosity solution will provide longer bulging times

does not by itself suggest chitosan or any particular derivatives should be used. There are numerous different agents that might be used to increase solution viscosity. Chitosan is but one polysaccharide, and the claimed derivative "containing carbohydrate chains" is but one way to derivatise chitosan. Other than suggesting it is analogous to the staples used in Onuki's suturing device, the Examiner has provided no reason why one of ordinary skill in the art would select chitosan or its derivatives to increase the saline-solution viscosity in Onuki. For example, other polysaccharides (e.g. glycosaminoglycans such as hyaluronic acid), proteins (e.g. collagen) and a near infinite array of other compounds all could be used to increase solution viscosity. There is no reason to select the claimed chitosan derivatives without referring first to the applicant's claims.

In view of the foregoing, it is respectfully submitted that it would not have been obvious to one of ordinary skill in the art, based on Onuki and Hirofumi, to substitute Hirofumi's chitosan compounds for the saline used in Onuki's injection needle 201. The other cited reference, Sung, is merely cited "to show that it is known that chitosan compounds can be delivered to the body using an endoscopic instrument." Office action, p. 5. In Sung, it is disclosed that a chitosan-drug-genipin compound can be delivered into the body via numerous devices, including an endoscopic instrument, as a carrier for the intended slow drug release. Sung, col. 8, lines 56-65. This does not suggest using chitosan compounds as bulging agents to be injected under a mucous membrane. Accordingly, for the foregoing reasons, it is respectfully submitted that the rejection of claim 16 has been overcome.

New claims 24-27 depend ultimately from claim 16 and further recite that the composition comprising the chitosan derivative "has a low viscosity of 300 cps (mPa•s) or less." This additional feature is believed to be separately patentable over the cited references for the followings reasons. The Examiner asserted that since Onuki et al.

discloses that the higher the viscosity of the solution, the longer the bulging time of the mucous membrane, it would have been obvious to replace the physiological saline in Onuki et al. with the chitosan derivative solution of Hirofumi et al., in order to increase viscosity of the solution. As already mentioned, the viscosity statement in Onuki does not by itself suggest using a chitosan-derivative solution. In addition, however, it has been discovered that a relatively *low-viscosity* solution of the chitosan derivative as-claimed will produce substantially prolonged bulging times compared to a higher-viscosity material (comprising hyaluronate). This is contrary to the basic teaching in Onuki that higher viscosity always produces higher bulging times. The present inventors considered that the bulging time can be prolonged by not only the viscosity of the solution but also the kind (property) of the solution. For example, in one example where hyaluronic acid (sodium hyaluronate) solution, having a viscosity higher than that of simple saline, was used as a bulging solution, bulging of mucous was decreased within only 30 minutes, whereas clear elevated shape was maintained even after 24 hours when using chitosan derivative solution (it was not photo-cross-linked) (Example 4 of the present specification and Figure 4).

Accordingly, the suggestion in Onuki et al. does not lead to use the chitosan derivative of Hirofumi et al. in place of the saline in Onuki et al. In contrast to the suggestions in Onuki et al., the bulging solution of the present invention preferably has a low viscosity (see [0035], lines 9-13). In order to emphasize and claim this additional feature, new claims 24-27 have been added to the application. Therefore, it is submitted that the suggestion in Onuki et al. that simple increase of viscosity results in prolonging bulging time, rather teaches away from using the low-viscosity solution of the present invention as recited in new claims 24-27.

Finally, it is further noted that Sung et al. simply disclose the delivery of drug included in a chemically cross-linked carrier material, wherein chitosan-genipin cross-

linked substance can be used as the carrier material. The carrier material in Sung et al. is solidified before it is delivered into the tissue of the patient. Accordingly, Sung et al. does not affect on the patentability of the present invention.

In light of the foregoing, it is respectfully submitted that the rejection of claim 16 has been overcome, and reconsideration and withdrawal of same is respectfully requested. In addition, new claims 24-27 are considered to be independently patentable for the reasons give above. All remaining claims are dependent claims and are believed to be allowable at least by virtue of their dependence from an allowable base claim.

Should the Examiner have any questions or concerns with respect to the instant submission, he is invited to initiate a telephone interview with the undersigned to expedite prosecution of the present application.

If there are any additional fees resulting from this communication, please charge same to our Deposit Account No. 16-0820, our Order No. WING1-40154.

Respectfully submitted,

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